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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

JONATHON LEE BOUTSIKARIS, a resident of Troy, Michigan,

Plaintiff,

v.

BAYER CORPORATION, an Indiana corporation, successor to CUTTER BIOLOGICAL, a California Corporation; BAXTER HEALTHCARE CORPORATION, a Delaware corporation, and its HYLAND DIVISION; ARMOUR PHARMACEUTICAL COMPANY, INC., a Delaware corporation and ALPHA THERAPEUTIC CORPORATION, a California corporation,

Defendants.

Case

COMPLAINT FOR DAMAGES AND INJUNCTIVE RELIEF

Jury Trial Demanded

(1) Negligence
(2) Negligence Per Se
(3) Fraudulent Omission and Concealment
(4) Breach of Implied Warranty

I. INTRODUCTION

1. Defendants manufactured blood products known as "Factor VIII" and "Factor IX" for the treatment of hemophilia, and sold these products to people with hemophilia in the United States and worldwide, despite knowledge that the products were manufactured from sick, high-risk donors and/or known to be contaminated with the virus that causes Non-A, Non-B Hepatitis (now known as "Hepatitis C" or "HCV"). Defendants knowingly declined to timely pursue or adopt treatment and manufacturing practices that would have prevented the infection of Plaintiff with HCV, as described in more detail below. Defendants also continued selling old stocks of products they knew to be contaminated with HCV even after they or others had

introduced safer products. Plaintiff is a person with hemophilia who contracted HCV through use of Defendants' contaminated products. This complaint describes the factual predicate for Plaintiff's infection: a pattern of foot-dragging, denial, and obfuscation by the pharmaceutical companies on whom his health and well-being depended.

2. Defendants manufactured HCV-contaminated blood factor products using human plasma taken from thousands of paid donors, including populations then known to be at high risk of carrying blood-borne diseases, such as urban homosexuals, prisoners, and intravenous drug users. Defendants intentionally recruited urban homosexuals who had a history of viral hepatitis as plasma donors, despite regulations prohibiting the use of such donors and despite knowledge that the virus that causes HCV was a blood-borne disease prevalent in such populations. Defendants continued using plasma taken from high-risk prison donors, even after promising the FDA that they would cease doing so. Through their trade associations, Defendants actively conspired to conceal these practices and to substantially delay product recalls and implementation of safety measures.

3. Defendants failed to fully and completely disclose the known risks of their products, including the risk of HCV; failed to implement readily available screening tests that would have prevented HCV by excluding contaminated plasma; failed to use available methods of treating plasma to kill viruses, including treatment with solvents and/or detergents; and concealed and affirmatively misrepresented the extent of the health dangers of the diseases caused by the products. Defendants also continued to sell old stocks of product that had not been treated even after introducing a safer treated product, including stocks that Defendants knew or had reason to know were made from pooled blood contaminated with HCV.

4. Defendants' efforts to maximize profits came at the expense of the health and lives of thousands of people with hemophilia in the United States and worldwide who were needlessly infected with HCV, including JONATHON LEE BOUTSIKARIS.

II. JURISDICTION AND VENUE

5. Plaintiff alleges an amount in controversy in excess of $75,000, exclusive of interest and costs. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiff and Defendants.

6. Plaintiff is informed and believes and on such information and belief alleges that the conduct by Defendants that is relevant to the subject matter of this action took place primarily in their respective headquarters location and in other facilities within the States of California and Illinois, giving these states significant contacts to the claims asserted by Plaintiff and creating state interests such that the choice of either or each of these states' laws to govern the adjudication of this action is neither arbitrary nor fundamentally unfair.

III. PARTIES

7. Plaintiff JONATHON LEE BOUTSIKARIS, a resident of Troy, Michigan who has hemophilia and was infected with HCV as a result of infusing Defendants' contaminated factor concentrate and/or as a result of Defendants' conspiracy. Plaintiff has already provided Defendants with a confidential Preliminary Patient Profile Form ("PPPF"), with beginning Bates number L-PPF 001909. The PPPF contains substantial additional information regarding Plaintiff's claim.

8. Plaintiff suffers from serious injuries and diseases, including HCV and associated symptoms, as a direct and proximate result of use of Defendants' blood products and Defendants' conspiracy.

9. Plaintiff would not have chosen to be treated with Defendants' blood products had he known of or been informed by Defendants of the true risks of using those products or the nature of the sources of the products.

10. Defendant CUTTER BIOLOGICAL ("CUTTER"), the predecessor of Miles, Inc., and Defendant BAYER, was a California corporation headquartered in Berkeley, California at all pertinent times. At all pertinent times CUTTER and its successors Miles, Inc. and BAYER regularly and systematically engaged in the harvesting and collection of human plasma and the processing, manufacturing, marketing, sales and distribution of factor

concentrates produced from such plasma, to which Plaintiff was exposed and which contributed directly or indirectly to Plaintiff's infection with HCV.

11. Defendant BAYER CORPORATION ("BAYER"), formerly Miles, Inc., is and was an Indiana corporation, authorized to do business in all 50 states and the District of Columbia. Miles, Inc. had its principal place of business operation in Elkhart, Indiana, while its successor BAYER has its principal place of business in Pennsylvania, with offices located at 100 BAYER Road, Pittsburgh, Pennsylvania 15205. At all pertinent times BAYER and its predecessors Miles, Inc., and CUTTER regularly and systematically engaged in the harvesting and collection of human plasma and the processing, manufacturing, marketing, sales and distribution of factor concentrates produced from such plasma, to which Plaintiff was exposed and which contributed directly or indirectly to Plaintiff's infection with HCV.

12. Defendant BAXTER HEALTHCARE CORPORATION ("BAXTER") is a Delaware corporation, authorized to do business in all 50 states and the District of Columbia, with its principal place of business in Illinois, with offices located at One Baxter Parkway, Deerfield, Illinois 60015. At all times pertinent, Defendant BAXTER, and/or its HYLAND DIVISION, had its main manufacturing plant in Glendale, California. At all times pertinent, Defendant BAXTER, and/or its HYLAND DIVISION, and/or its wholly owned subsidiaries Travenol Laboratories, regularly and systematically engaged in the harvesting and collection of human plasma and the processing, manufacturing, marketing, sale and distribution of FACTOR CONCENTRATE products produced from such plasma, to which Plaintiff was exposed and which contributed directly or indirectly to Plaintiff's infection with HCV.

13. Defendant ARMOUR PHARMACEUTICAL COMPANY, INC. ("ARMOUR") is a Delaware corporation, with its principal place of business in Pennsylvania, with offices located at 500 Arcola Road, P.O. Box 1200, Collegeville, Pennsylvania, 19426-0107. At all times pertinent, ARMOUR regularly and systematically engaged in the harvesting and collection of human plasma and the processing, manufacturing, marketing, sales and distribution of factor concentrate products produced from such plasma, to which Plaintiff was exposed and which contributed directly or indirectly to Plaintiff's infection with HCV.

14. Defendant ALPHA THERAPEUTIC CORPORATION ("ALPHA") is a California corporation, with its principal place of business in California, with offices at 5555 Valley Boulevard, Los Angeles, California 90032. At all times pertinent, Defendant has been regularly and systematically engaged in the harvesting and collection of human plasma, and the processing, manufacturing, marketing, sale and distribution of factor concentrate products produced from such plasma, to which Plaintiff was exposed and which contributed directly or indirectly to Plaintiff's infection with HCV.

15. Defendants CUTTER, BAXTER, ARMOUR and ALPHA (hereinafter collectively referred to as "Defendants"), acting on behalf of themselves and/or their predecessor and/or successor corporations, collected, harvested and/or processed human plasma and/or manufactured, marketed, sold and distributed factor concentrate products that were contaminated with HCV. In the alternative, one or more of said Defendants participated in the collection, harvesting and/or processing of human plasma, and/or the manufacturing, marketing, distribution and sale of factor concentrate products, that were contaminated with HCV; or assumed or became responsible for, the liabilities of the Defendants and their predecessor or successor corporations who did participate in the collection, harvesting and/or processing of human plasma, and/or the manufacturing, marketing, distribution or sale of factor concentrate products, that were contaminated with HCV, without limitation thereto.

16. At all times herein mentioned, Defendants were fully informed of the actions of their agents and employees, and thereafter no officer, director or managing agent of Defendants repudiated those actions, which failure to repudiate constituted adoption and approval of said actions, and Defendants thereby ratified those actions.

IV. FACTUAL ALLEGATIONS

A. Hemophilia and Its Treatment

17. Hemophilia is an inherited condition that causes uncontrolled hemorrhaging or bleeding. Hemophilia results from a deficiency of blood components essential for coagulation. The most common form of the disease is hemophilia A, characterized by a lack

of a blood protein known as Factor VIII, which affects approximately one in 10,000 males. Factor VIII is commonly called "AHF" or anti-hemophilic factor. Hemophilia B is characterized by absence of another blood protein, known as Factor IX, affecting about one in 40,000 males. Plaintiff JONATHON LEE BOUTSIKARIS has mild hemophilia A.

18. The treatment of hemophilia involves intravenous introduction, called infusion, of the missing blood proteins required to stop bleeding. The two most prevalent forms of such treatment are cryoprecipitate and factor concentrates. Factor concentrates are the products made by Defendants in this action. Cryoprecipitate is made by freezing plasma, the fluid component of circulating blood in which various proteins, including Factor VIII and Factor IX, are contained; thawing the frozen plasma; and isolating Factor VIII from the plasma through centrifugal concentration. Cryoprecipitate is an effective therapeutic agent for patients with hemophilia A. Hemophilia B has been effectively treated with the use of fresh frozen plasma containing Factor IX. Cryoprecipitate and fresh frozen plasma are made from small numbers of donors, who are generally unpaid volunteers.

19. In the late 1960s to early 1970s, Defendants began to market factor concentrates, which contained Factor VIII and Factor IX in higher concentrations than had been available in either cryoprecipitate or fresh-frozen plasma. To produce factor concentrates, Defendants mixed pools of plasma from five to over twenty thousand donors at a time, a large percentage of which were paid donors. These large pools were then subjected to processes to concentrate Factors VIII and IX.

B. Defendants Failed to Disclose or Warn of Serious Adverse Effects Associated with Factor Concentrates

20. Shortly after the initial commercial marketing of Factor VIII and IX concentrates in the late 1960s to early 1970s, a wide range of serious adverse effects were reported in association with these products. By that time, Defendants knew of serious diseases caused by unidentified agents transmissible by blood and Factor VIII and IX. Defendants failed to warn Plaintiff or the medical community of these adverse effects, violating industry standards and federal regulations.

21. By 1976, only a few years after Defendants' factor concentrate products went on the market, the United States Food and Drug Administration ("FDA") Bureau of Biologics held a conference titled *Unsolved Therapeutic Problems in Hemophilia.* The research articles compiled from the conference discussed the high incidence of disorders in patients using Defendants' products, such as liver dysfunction, enlarged spleen, Hepatitis B, and Non-A, Non-B Hepatitis ("NANB Hepatitis," later renamed Hepatitis C). The articles concluded that these disorders were tied to the patients' use of factor concentrates, and emphasized the risks entailed in producing such concentrates using plasma from paid donors. For instance, Robert Gerety of the FDA Bureau of Biologics, Division of Blood and Blood Products, reported that the agent or agents of NANB Hepatitis "appear to be blood borne, perhaps to be associated with a form of chronic hepatitis, and to represent a considerable risk to recipients who repeatedly require the administration of blood products." Gerety, et al., *Viral Antigens and Antibodies in People with Hemophilia* (1977). Gerety noted that "[t]he use of large plasma pools from paid donors no doubt contributes to the risk of HBV [Hepatitis B] infection from these products," and stated that "an all voluntary blood donor system is being pursued as a result of the known increased risk of PTH [post-transfusion hepatitis] from blood derived from commercial donors." As described below, however, Defendants not only refused to implement such a voluntary donor system, but instead recruited paid donors precisely because their hepatitis exposure resulted in plasma from which Defendants could make other commercially valuable products as well.

22. At all times material to this Complaint, Defendants failed to adequately warn Plaintiff or his physicians of the serious adverse side effects of their products. Although Defendants' package inserts mentioned a risk that plasma "may" contain the causative agent of viral hepatitis, this warning was seriously deficient in that: (a) Defendants failed to disclose that the risk of hepatitis was essentially a 100% guarantee due to their practices of using high-risk donors and specifically recruiting for donors who had previously been exposed to Hepatitis B; (b) while "hepatitis" simply means inflammation of the liver, and may be a relatively benign, temporary condition, Defendants failed to warn that some forms of hepatitis transmitted by their products were believed to present a considerable risk of severe liver damage and a significantly

elevated risk of liver cancer; (c) Defendants misleadingly stated that the source plasma used in preparation of their products had been found to be non-reactive for Hepatitis B surface antigen (HBsAg)—implying that no viral hepatitis was present in the plasma—and falsely stated that available methods were not sensitive enough to detect all units of potentially infectious plasma, failing to disclose that in fact Defendants had refused to implement the more sophisticated Hepatitis B Core antibody (HBc) test which would have excluded the majority of plasma contaminated by hepatitis; and (d) Defendants' labeling disclosed that their products were made from large pools of fresh human plasma, but failed to disclose that paid donors increased the risk of disease, and that the particular groups of paid donors targeted by Defendants were known to be the highest risk groups.

23. The demand for and supply of anti-hemophilic factor rapidly increased during the 1970s, with commercially-manufactured concentrate accounting for a large proportion of the increase in supply. In 1977, a federal report projected that the volume of factor concentrates manufactured would increase substantially by 1980. Division of Blood Diseases and Resources, National Heart, Lung and Blood Institute, *Study to Evaluate the Supply-Demand Relationships for AHF and PTC Through 1980*, at page 8; hereinafter "NHLBI Report."

24. In order to sell more factor concentrates to this growing market, Defendants turned to the fastest and cheapest way of obtaining sufficient plasma, paid donors. Defendants recruited paid donors from those populations most likely to respond to the financial incentive to donate: poor inner city residents, drug abusers, prisoners, and residents of impoverished developing countries such as Haiti and Nicaragua.

25. Defendants purposefully sought out paid donors despite knowing that the risk of diseases transmissible by blood was far greater among paid donors than among volunteers. Because no test was yet available in the 1970s for the NANB Hepatitis virus, an essential means to prevent the virus from contaminating the plasma supply was to exclude donors with behaviors that were inconsistent with good health—precisely those populations from which Defendants were recruiting paid donors. Some studies indicated that paid donors were up to ten times more infectious than volunteer donors. For this reason, the National Blood Policy, adopted by the

federal government in July 1973, advocated conversion to an all-volunteer blood supply. Defendants, however, not only continued to use paid donors, but also focused their recruiting efforts on the highest risk populations.

26. Defendants had an additional financial incentive for recruiting paid donors. Factor VIII and Factor IX are only two of many products that can be made for commercial sale from human plasma. According to the NHLBI Report, by the late 1970s at least 17 different therapeutic components of blood were manufactured by the process of "fractionating" plasma into its various elements. The NHLBI Report noted that, "as the costs of fractionation have increased, fractionators have produced as many products as possible from a liter of plasma." *Id.* at 65.

27. Blood derivatives used as vaccines or therapeutics had particularly high economic value for Defendants. The NHLBI Report noted that plasma with a very high titer, or antibody level, for a corresponding antigen is "very expensive." *Id.* at 41. Such products are manufactured from source plasma drawn from donors who have been sensitized to a particular antigen. *Id.* The NHLBI Report specifically stated, however, that "plasma collected for high antibody titer **cannot** be used for fractionation into therapeutic products," such as Defendants' factor concentrate. *Id.* (emphasis added).

28. Defendants targeted donors with high titers to Hepatitis B antigens in order to manufacture and sell Hepatitis B immunoglobulin (HBIG), a product that confers temporary immunity to the Hepatitis B virus. Despite the warning in the NHLBI report, Defendants used the same high-titer plasma obtained for making HBIG to manufacture their Factor VIII and IX products used by people with hemophilia. Defendants thus sought to maximize profits by producing "as many products as possible from a liter of plasma," while ignoring industry standards that precluded the use of high-titer plasma for other therapeutic products.

29. Beginning in about 1978, Defendants began targeting homosexual donors in known urban gay communities. Because urban homosexuals had been reported in the 1970s to have exceptionally high prevalence of Hepatitis B infection, Defendants knew that such donors would provide a reliable source of plasma for the manufacture of commercially valuable HBIG.

30. By the 1970s, it was also well-known in the public health community that urban homosexuals engaged in promiscuous sexual practices that rapidly transmitted other diseases, including NANB Hepatitis, which were transmitted by blood and were believed to have serious adverse consequences. Despite this knowledge, Defendants used the same plasma pool from urban homosexuals to manufacture both HBIG and Factor VIII and IX.

31. By the 1970s, it was also well-established that plasma from prison populations carried a high risk of hepatitis and other blood-borne diseases, primarily because of the concentration of intravenous (IV) drug users in prisons. By 1974, the alanine aminotransferase ("ALT") test was available to test for elevated levels of liver enzymes called SGOT that indicate the presence of hepatitis. Prisoners were associated with SGOT levels of over 60 IUs per ml, a level that increases the risk of Hepatitis C transmission by a factor of 6. Despite knowledge of this risk, Defendants actively recruited prisoners for plasma used to manufacture Factor VIII and IX, while concealing or failing to disclose the risk to Plaintiff, his physicians, or the FDA.

32. In light of Defendants' special knowledge of the disease patterns among urban homosexuals and prisoners, and their recruitment of such donors for Factor VIII and IX manufacture, Defendants had duties to: (a) discontinue the practice of using such high risk donors; (b) disclose the risk to Plaintiff, his physicians, and the FDA, including the ongoing risk of continuing to use Factor VIII and IX previously manufactured with high risk plasma and still marketed to patients; (c) implement procedures to kill blood-borne diseases in the products; and (d) recall existing products from distribution or further use. Instead, Defendants continued to conceal their recruitment of high-risk donors and to resist warnings and recalls, and failed to implement procedures to make their products safe.

33. By no later than 1978, Defendants knew of the availability of a new test to determine whether an individual had a history of viral hepatitis, which would have disqualified the donor from providing plasma for the manufacture of Factor VIII or IX. By testing a person's serum for the presence of the core to the Hepatitis B antibody, a history of viral hepatitis could be verified. This was known as the "HBc test." Published, peer-reviewed literature shows that the

HBc test was in use by researchers to determine that homosexual AIDS victims had a history of viral hepatitis by no later than December 1981. Gottlieb, et al., *Pneumocystis Carinii Pneumonia and Mucosal Candidiasis in Previously Healthy Homosexual Men,* 305 New Eng. J. Med. 1425-1431 (1981).

34. Use of the HBc test would have eliminated approximately 75% of homosexual plasma donors and over 90% of promiscuous urban homosexuals. It would have eliminated almost 100% of intravenous drug users.

35. Use of the HBc and ALT tests together by Defendants by 1981 would have eliminated the vast majority of the transmitters of HCV from the blood and plasma pools of the nation, before the height of the Hepatitis C epidemic. If Defendants had implemented this test in a timely manner, Plaintiff more likely than not would not have been infected with HCV as a result of factor concentrate use.

36. As noted below, federal regulations required plasma donors to be in good health, and donors with a "history of viral hepatitis" were by definition unacceptable as blood or blood plasma donors. Persons with a history of viral hepatitis were excluded not only because of the risk of transmitting Hepatitis B, but because such a history indicated a lifestyle or previous behavior of the prospective donor that carried the risk of transmitting other viruses in addition to hepatitis. A reasonable and prudent plasma fractionator would not accept a HBc positive donor and expect to be in compliance with federal regulations as of 1978.

37. After public reports of the first hemophilia AIDS cases in July 1982, government officials urged Defendants to implement the HBc test as a "surrogate" or "marker" to eliminate plasma contaminated by the transmitter of AIDS and Hepatitis C. HBc testing was also strongly suggested to Defendants by the CDC at a meeting of the United States Public Health Service ("PHS") on January 4, 1983. Despite this urging, Defendants continued to use contaminated plasma donations that would have been excluded by the HBc test and continued to conceal from Plaintiff, his physicians, and the FDA the dangerous practice of targeting donors at highest risk for hepatitis. At a January 6, 1983 meeting of Defendants' trade association, the Pharmaceutical Manufacturer's Association, Defendants agreed not to implement the highly

effective HBc donor screening, and instead opted to use ineffective donor questionnaires that did little to screen out donors at high-risk for Hepatitis C transmission.

38. As late as December 13, 1983, years after the HBc test was available, a memorandum from CUTTER's responsible head, Stephen Ojala, reporting back on a meeting held by Defendants, shows that Defendants conspired to propose a "task force" to further study the use of HBc as an intentional, bad faith "delaying tactic for the implementation" of the test.

C. Defendants Also Declined to Implement Available Treatment With Solvents and/or Detergents to Kill Blood-Borne Diseases, and Continued to Dump Contaminated Product on the Market After Safer Product Was Available

39. In the late 1970s and early 1980s, it was recognized that viruses were in all factor concentrate products. Treatment with solvents and/or detergents was available at that time to eliminate many of these viruses, including HCV. Defendants were required to take reasonable steps to eliminate contamination, but Defendants failed to utilize these available technologies to eliminate the viruses in a timely manner.

40. Solvent and/or detergent treatment was available to Defendants by the late 1970s as a simple and effective method of eliminating viruses in factor concentrate products. Solvents and/or detergents effectively kill viruses such as HCV by destroying the viruses' lipid envelope. This method is simpler than heat treatment, and unlike heat treatment does not interfere with the Factor VIII and IX proteins needed for blood clotting.

41. Solvents and/or detergents were well-known, commercially available products as of the 1970s, and studies in which solvent and/or detergent treatment was used to disrupt viruses were published in the 1970s in peer-reviewed journals. In 1980, Dr. Edward Shanbrom, a former Baxter scientist, received a patent for a detergent treatment process for viral inactivation of factor concentrate. Dr. Shanbrom describes the implementation of this process as "as easy as washing your hands."

42. After receiving the patent, Dr. Shanbrom approached Defendants about implementing his method, but Defendants refused to heed Dr. Shanbrom's advice. Defendants refused to even commit any resources to investigate the solvent and/or detergent method.

43. Defendants were notified of the successful use of organic solvents to destroy lipid viruses, including NANB, in factor concentrates by the New York Blood Center ("NYBC") at the National Hemophilia Federation's meeting on October 27, 1983.

44. In 1984, Dr. Prince and Dr. Horowitz of the NYBC published the results of their successful use of the solvent detergent process in well-known medical journals. They offered to license the process to Defendants for a reasonable fee. In 1985, the NYBC obtained a license from the FDA to market a solvent detergent inactivated factor concentrate.

45. By March, 1984, Defendants obtained licenses to sell Factor VIII treated with dry heat to inactivate viruses, and Defendants had obtained such licenses for Factor IX by October, 1984. The FDA did not allow them to label these products as hepatitis safe. By fall of 1984, Defendants were notified by treaters that previously-untreated patients in their clinical trials using their dry heated products developed elevated ALT enzymes, indicative of NANB infections.

46. Defendants were therefore aware in 1984 that dry heat did not effectively inactivate the virus that causes HCV, and that solvent detergent treatment methods did eliminate the risk of HCV infection, but chose not to employ the effective and efficient solvent detergent technology. Instead, Defendants continued to sell their contaminated dry heat product for at least four more years, resulting in the needless infection of Plaintiff and many other hemophiliacs.

47. A recent CDC study documented the comparative effectiveness of the dry heat and solvent detergent inactivation methods. The study reported that "84% of previously untreated patients infused with dry-heated Factor VIII products developed non-A, non B hepatitis… ." Soucie, Richardson, Evatt et al., *Risk Factor for Infection with HBV and HCV in a Large Cohort of Hemophiliac Males*, 41 Transfusion 338-343 (2001).

48. The same CDC study reported that "solvent detergent treatment of blood components [was] found to be more effective against enveloped viruses than heat treatment ... No cases of HBV, HCV, or HIV transmission through solvent detergent virus inactivated products have been found in prospective studies of previously untreated patients..."

49. The study further reported "in our data, the first dramatic decline in HCV prevalence appears in the 1987 birth cohort. The drop in HCV transmission correlates with the licensing of solvent detergent treatment of Factor IX products in 1987. In addition, this cohort would have been the first to benefit from the screening of blood donors using the surrogate markers ALT (begun in late 1986) and anti-HBc (begun in 1987), testing that was associated with a markedly decreased risk of HCV infection from blood transfusions."

50. The study states further that "the residual transmissions after 1987 possibly represent the use of product already manufactured or product manufactured during the interval required to implement the new technology. The 18-month shelf life of factor concentrates placed those people with hemophilia born as late as 1989 at risk of infection." The study goes on to recommend testing for all people with hemophilia who received infusions of Defendants' blood products prior to 1992.

51. By 1988, it was clear to the medical and scientific community what Defendants had long known: dry-heated factor concentrates were transmitting the potentially deadly NANB virus, and safer products were available. This knowledge prompted the CDC to publish recommendations that dry-heated products no longer be used by hemophiliacs. Defendants continued sales of their dry-heated products after these warnings, however, and never undertook a large-scale recall of dry-heated product. Defendants finally introduced solvent detergent-treated products to the market in 1988 and 1989, but continued to sell their NANB-contaminated dry-heated factor concentrates after this date.

52. The failure of Defendants to implement solvent and/or detergent viral inactivation techniques in a timely manner, to warn of the risk that dry heat treated Factor VIII and IX blood products could transmit HCV, and to recall dry heat-treated products that posed this risk caused the needless infection of thousands of people with hemophilia with HCV, including Plaintiff. Even after Defendants knew or should have known that solvent and/or detergents effectively destroyed HCV, they continued to sell dry heat-treated Factor VIII and IX, and refused to recall these dangerous products from the market.

D. Defendants Fraudulently Misrepresented the Safety, and Concealed the Dangers, of Their Factor VIII and IX Products

53. Defendants engaged in a pattern and practice of fraudulent concealment of their dangerous practices, fraudulent misrepresentations regarding their efforts to assure safety, and fraudulent misrepresentations regarding the risk of Hepatitis C, in order to maintain profits from both factor concentrates and HBIG. A summary of Defendants' fraudulent misrepresentations and concealment is set forth below.

54. On July 27, 1982, a meeting of the Public Health Service was held as the result of the CDC's report that three people with hemophilia had contracted AIDS. The responsible heads of Defendants were in attendance, along with officials from the National Hemophilia Foundation, CDC and FDA. Defendants were aware that they had used plasma from known, targeted homosexuals in the manufacture of their Factor VIII and IX blood products. These products had a shelf life of two years and were either in production or already on the shelves in pharmacies waiting to be infused by people with hemophilia who purchased them. Defendants failed to disclose these facts at the meeting where CDC officials were present, despite knowledge that the CDC's primary concern at that meeting was the contamination of Factor VIII and IX by the agent that transmitted AIDS, which, like hepatitis, was already well-known to be epidemic in the targeted homosexual population. (CUTTER memorandum dated August 3, 1982.)

55. In or about December, 1982, Rodell, the responsible head for BAXTER, entered into an agreement with officials of the FDA to the effect that BAXTER would no longer use prison plasma in the production of factor concentrates. In fact, BAXTER, unbeknownst to the FDA, continued to use prison plasma in factor concentrate production through October 1983. BAXTER memorandum dated October 20, 1983.

56. On January 5, 1983, an AIDS meeting was held at Children's Orthopedic Hospital in Los Angeles, California, the largest hemophilia treatment center in the United States. Representatives of Defendants were present at the meeting with treaters and patients. A patient asked representatives from Defendants the following question: "Is the plasma from homosexuals,

prisoners, Haitians or other high risk persons being used in the manufacture of concentrates?" Defendants did not admit targeting or using plasma from homosexuals, prisoners or inner city IV drug abusers. Defendants' representatives made no response to the question, thereby concealing the true risk created by the use of plasma from known homosexuals, IV drug abusers and prisoners in the manufacture of factor concentrates.

57. At the January 5, 1983 meeting, and in the presence of the patients, one of the treating physicians, Dr. Kasper, asked CUTTER's Stephen Ojala: "These [plasma] centers seem to be in rundown centers of town. Is there a move to move them to rural towns?" Ojala answered: "Many of the centers are in smaller communities and in towns such as Ypsilanti, Seattle, Clayton, NC., and San Diego. We do not have centers in L.A. or San Francisco." This answer was misleading because Ojala failed to state that CUTTER's largest and first plasma center was located at Arizona State Penitentiary. CUTTER also had a center at the Las Vegas Prison. Ojala and CUTTER were well aware of the CDC's and FDA's concern over use of prison plasma, due to homosexual practices and drug abuse in the prison donor population. Many of CUTTER'S centers were in inner city areas frequented by IV drug abusers, such as downtown Oakland, California. CUTTER had also used plasma from centers which targeted known homosexuals. In August 1982, CUTTER quarantined plasma from the Valley Medical Center, a center which targeted known homosexuals, because a donor was hospitalized with full blown AIDS. The plasma was intended for factor concentrate and HBIG production, but was not used because it had thawed on the way to the processing plant. Upon receiving a report of this incident from CUTTER, the FDA indicated a recall might have been necessary if the plasma had been incorporated into factor concentrate final product. Ojala omitted any mention of these facts and circumstances in his response to Dr. Kasper regarding the location of their plasma centers. (CUTTER memorandum dated January 5,1983.)

58. On January 14, 1983, responsible heads from Defendants attended a meeting of the National Hemophilia Foundation ("NHF"). Defendants were very concerned that the NHF would insist on a recommendation that HBc testing be implemented, consistent with the CDC recommendation 10 days earlier. In order to defer a NHF recommendation that HBc testing

be used, Michael Rodell, a representative of BAXTER, told NHF officials on behalf of Defendants, that surrogate testing was in the "R and D," or "Research and Development," stage currently. Rodell concealed the fact that the CDC had strongly recommended use of the HBc antibody test as a screening device for high risk donors. The HBc antibody test was not in the "R and D" stage, and was suitable for use as a screening device for high risk AIDS and Hepatitis C donors. In fact, the HBc test had been approved in 1979 by the FDA as a test to be used to ascertain a history of previous hepatitis B infection, and to screen blood and plasma donors. Donors with a hepatitis history were specifically prohibited pursuant to the federal regulations (21 C.F.R. § 640.63). Rodell acknowledged that implementation of the HBc test would eliminate high titered immunoglobulin donors, but failed to disclose that opposition to use of the test was based on economic rather than safety concerns.

59. At the January 14, 1983 meeting, Defendants concealed their advertising in publications distributed among urban homosexuals, for the specific purpose of attracting them to plasma centers which supplied high titered plasma to Defendants. Defendants also concealed their extensive use of prison plasma, and failed to reveal their "gentlemen's agreement" with the FDA to discontinue use of these plasma sources immediately. (CUTTER Memorandum dated January 17, 1983.)

60. On or about December 15, 1983, Rodell, then the head of Armour Pharmaceutical Company, Inc., told members of the federal Blood Product Advisory Committee (BPAC) and FDA officials that Defendants wanted a three-month deferral in implementation of any recommendations by the BPAC or FDA that HBc testing be required for plasma donors. Rodell told the FDA that the purpose of the deferral was to prepare a response to the proposed recommendation. In fact, Defendants had agreed to seek the three-month hiatus as a "delaying tactic" to avoid implementing the test, and the request for a deferral was made in bad faith. (CUTTER memorandum dated December 13, 1983.)

61. Defendants fraudulently misrepresented the risk of Hepatitis C due to factor concentrates, failed to disclose accurate warnings of the risk to Plaintiff or his physicians, and fraudulently purported to be doing "everything possible" to improve safety, when in fact

Defendants maximized the risk by recruiting high-risk donors and by resisting and obstructing HBc testing, treatment with solvents and/or detergents, and other measures that would truly have reduced the risk.

E. Defendants' Activities Were Subject to Applicable Federal Regulations, Which Evidence the Standard of Care With Which Defendants Should Have Complied

62. Blood derivatives such as Factor VIII and IX are prescription biologicals subject to federal regulation as both "biological products" and "drugs." Public Health Service Act, "Regulation of Biological Products," 42 U.S.C. § 262; Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq. (2005).*

(a) 21 U.S.C. § 331(b) prohibited and continues to prohibit "adulteration or misbranding of any ... drug . . . ."

(b) 21 U.S.C. § 351(a)(2)(B) provided and continues to provide that "[a] drug . . . shall be deemed to be adulterated . . . if . . . the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety. . . ."

(c) 21 U.S.C. § 352 provided and continues to provide that "[a] drug... shall be deemed to be misbranded. .. if its labeling is false or misleading in any particular."

(d) 21 U.S.C. § 352(f)(2) provided and continues to provide that a drug shall be deemed to be "misbranded" unless its labeling bears "adequate warnings against use. .. where its use may be dangerous to health."

(e) 21 U.S.C. § 352(n) provided and continues to provide that a drug shall be deemed to be "misbranded" unless the labeling included information concerning side effects and contraindications as required in federal regulations.

(f) 21 U.S.C. § 321(n) provided and continues to provide that if an article is alleged to be misbranded because the labeling or advertising is misleading, then the determination of whether the labeling or advertising is misleading shall take into account "not only representations made or suggested" by affirmative statements, "but also the extent to which

the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use" of the drug.

63. At all times material to this Complaint, 21 C.F.R. § 201.57(e) provided and continues to provide as follows, with respect to information to be provided with the sale of Defendants' products:

> Warnings: Under this section heading, the labeling shall describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur. The labeling shall be revised to include a warning as soon as there is reasonable evidence of an association with a drug; a causal relationship need not have been proved.

64. At all times material to this Complaint, 21 C.F.R. § 200.5 provided and continues to provide as follows:

> Manufacturers and distributors of drugs and the Food and Drug Administration occasionally are required to mail important information about drugs to physicians and others responsible for patient care. In the public interest, such mail shall be distinctive in appearance so that it will be promptly recognized and read.

65. At all times material to this Complaint, Part 606 of 21 C.F.R. set forth and continues to set forth "Current Good Manufacturing Practices" for biological products generally, and 21 C.F.R. § 640, *et seq.*, set forth additional good manufacturing practices for blood and plasma biologicals.

66. At all times material to this Complaint, 21 C.F.R. § 606.140(a) provided and continues to provide:

> Laboratory control procedures shall include: The establishment of scientifically sound and appropriate specifications, standards and test procedures to assure that blood and blood components are safe, pure, potent and effective.

67. At all times material to this Complaint, 21 C.F.R. § 640.60 defined and continues to define "Source Plasma" as:

> the fluid portion of human blood collected by plasmapheresis, and is intended as source material for further manufacturing use.

68. At all times material to this Complaint, 21 C.F.R. § 640.63(c), (1999), titled "Qualification of Donor," provided and continues to provide as follows with respect to donors of source plasma:

> Donors shall be in good health on the day of donation, as indicated in part by: . . . (9) freedom from any disease, other than malaria, transmissible by blood transfusion, in so far as can be determined by history and examination indicated in this section; (10) freedom of the arms and forearms from skin punctures or scars indicative of addiction to self-injected narcotics; (11) freedom from a history of viral hepatitis; (12) freedom from a history of close contact within six months of donation with an individual having viral hepatitis; . . . .

Further, 21 C.F.R. § 640.63(a) provided and continues to provide that the method of determining "suitability of a donor" included "tests" as well as the taking of a history and physical examination.

69. The foregoing statutes and regulations are evidence of the standard of care Defendants should have employed in the manufacture and sale of Factor VIII and Factor IX. Defendants violated the foregoing regulations and/or failed to comply with applicable standards of care by: (a) marketing "adulterated" products that were unsafe as a result of failure to comply with "Current Good Manufacturing Practice"; (b) marketing "misbranded" products that were misleading and failed to disclose or warn of health dangers; (c) failing to warn of serious adverse reactions and potential safety hazards as soon as there was reasonable evidence of an association with their products; (d) failing to exclude intravenous drug users who were unsuitable donors; (e) failing to exclude donors with a history of viral hepatitis who were unsuitable donors; (f) affirmatively seeking out unsuitable donors known to have viral hepatitis antibodies, as well as prison populations known to include substantial numbers of intravenous drug users, for inclusion of their plasma in the pools used to make Factor VIII and Factor IX; (g) failing to disclose their use of dangerous donors; and (h) failing to use appropriate tests and/or procedures to assure their products were safe.

F. Conspiracy, Concert of Action and Group Liability

70. Defendants acted in concert and participated in a conscious and deliberate conspiracy to act negligently, fraudulently and with willful and wanton disregard for the rights

and safety of blood product users, in connection with the manufacture of Factor VIII and IX blood products and the collection of constituent plasma.

71. Defendants herein tacitly and explicitly agreed to avoid upgrading industry standards. For example, the technology to virally inactivate factor concentrates existed in the early 1970s, but was not seriously investigated by any Defendant until the 1980s, despite its effective use in Europe. Likewise, use of the HBc antibody test to eliminate Hepatitis B carrier donors, and to identify donors with a history of viral hepatitis, was known science by 1978. The HBc test was reported to be an effective surrogate test for both AIDS and NANB Hepatitis carriers by 1982, yet no Defendants implemented this test until April 1984.

72. Several of the Defendants intentionally used donors from predominantly homosexual donor centers, prisons, and inner city areas where the risk of IV drug abuse was high. After July 1982, when the results of this conduct culminated in reports of fatal immune suppression in three people with hemophilia who infused the product, this concert of action took on a more overt, active form.

73. By December 1982, the FDA demanded that Defendants stop using prisoners, donors from high-risk areas for hepatitis and AIDS transmission, and known homosexuals. Rather than use good faith efforts to comply with the FDA's requests, Defendants collectively argued for a far less onerous and less effective donor screening program. At a January 6, 1983 meeting of Defendants' trade association, the Biological Section of the Pharmaceutical Manufacturer's Association ("PMA"), Defendants agreed not to implement highly effective HBc donor screening, instead selecting ineffective donor questionnaires that did little to screen out donors at high risk for NANB transmission. Defendants further agreed to keep each other informed as to what they were doing in order to maintain a low standard of care.

74. HBc testing had been strongly suggested by the CDC at the January 4, 1983 Public Health Service ("PHS") meeting. On January 14, 1983, Defendants acted jointly to persuade the National Hemophilia Foundation ("NHF") not to advocate surrogate testing for AIDS and Hepatitis C through implementation of the HBc test. Defendants persuaded the NHF that use of the HBc test was in the "R and D" stage and not practical to implement at that time.

On December 13, 1983, Stephen Ojala, CUTTER's responsible head, documented by written memorandum that Defendants met and jointly agreed to propose a "study" of the HBc surrogate screening test, as a "delaying tactic" to avoid implementing the HBc test.

75. Thereafter, at various times throughout 1983-1985, Defendants attended meetings or otherwise communicated to assure joint efforts to avoid recalling product; to avoid warning patients of the true risk; to market product when sales dropped due to information in the lay press related to viral transmission through factor concentrates; to avoid implementation of the HBc test; and to coordinate a joint legal defense plan in anticipation of litigation from patients infected by AIDS and NANB through use of the products. Defendants also operated through trade organizations, such as ABRA and PMA, to issue public statements minimizing the risk of Hepatitis C and overpromoting the benefits of factor concentrate, and to carry out the abovementioned goals of all Defendants.

76. All Defendants likely to have caused the harm to Plaintiffs are parties to this lawsuit and properly before the court.

77. The conduct of Defendants, with respect to their Factor VIII and Factor IX products and related plasma collection methods, was tortious.

78. The harm which has been caused to Plaintiffs resulted from the conduct of one, or various combinations of the Defendants, and, through no fault of Plaintiffs, there may be uncertainty as to which one or combination of Defendants caused the harm.

79. The burden of proof should be upon each Defendant to prove that the Defendant has not caused the harms suffered by Plaintiffs.

80. Factor concentrates were manufactured using the same fractionation method by all Defendants. As such, during the relevant years, factor concentrates were a fungible product, and physicians prescribed the products interchangeably without regards to brand names.

81. The factor concentrates manufactured by Defendants contained the same design flaws. They were all manufactured from paid donor plasma, which was at highest risk for Hepatitis B and Hepatitis C viral transmission. In addition, all Defendants' factor concentrates were made from large pools consisting of 5,000 to over 20,000 paid donors, which further

magnified the risk of viral transmission.

82. None of the factor concentrates made by Defendants during the relevant time period were subjected to viral inactivation processes such as solvent and/or detergent treatment that were effective against HCV. Therefore, all of Defendants' factor concentrates carried a significant risk of HCV transmission during this time. In addition, all of Defendants' factor concentrate products were similarly misbranded. All of the products failed to warn of the known risks enumerated in this complaint.

V. TOLLING OF APPLICABLE STATUTES OF LIMITATION

83. Any and all potentially applicable statutes of limitations have been tolled by Defendants' affirmative and intentional acts of fraudulent conduct, concealment, and misrepresentation, alleged above, which estop Defendants from asserting statutes of limitation. Such acts include but are not limited to intentionally covering up and refusing to disclose use of high-risk plasma; selling products known to be contaminated; suppressing and subverting medical and scientific research; and failing to disclose and suppressing information concerning the risk of HCV transmission from Defendants' contaminated factor concentrates.

84. Defendants are estopped from relying on any statutes of limitation because of their fraudulent concealment and misrepresentation alleged above. Defendants were under a duty to disclose the precise risks of HCV transmission from their contaminated factor concentrate because this is nonpublic information over which they had exclusive control, because Defendants knew this information was not readily available to people with hemophilia like Plaintiff, and because this information was relevant to such people in deciding whether to use Defendants' factor concentrate.

85. Until very recently, Plaintiff had no knowledge that Defendants were engaged in much of the wrongdoing alleged herein. Because of the fraudulent and active concealment of the wrongdoing by Defendants, including but not limited to deliberate efforts—which continue to this day—to give Plaintiff the materially false impression that Defendants undertook all feasible safety precautions to reduce the risk of HCV transmission from their contaminated factor concentrates, Plaintiff could not reasonably have discovered the wrongdoing

any time prior to this time, nor could Plaintiff have, as a practical matter, taken legally effective action given the unavailability, until very recently, of internal memoranda and other documents (as generally described herein) as evidence in support of Plaintiff's claims. Defendants still refuse to admit and continue to conceal their wrongdoing, and therefore Defendants' acts of fraudulent concealment and misrepresentation continue through the present time.

VI. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

FRAUDULENT OMISSION AND CONCEALMENT

86. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further alleges as follows:

87. Defendants had a confidential and special relationship with Plaintiff due to: (a) Defendants' vastly superior knowledge of the health and safety risks relating to Factor VIII and Factor IX; (b) Defendants' sole and/or superior knowledge of their dangerous and irresponsible plasma collection practices; and (c) Defendants' direct communications with the hemophiliac community through newsletters that purported to accurately convey the risk of NANB. As a result, Defendants had an affirmative duty to fully and adequately warn the hemophiliac community, including Plaintiff and physicians, of the true health and safety risks related to their Factor VIII and Factor IX blood products and constituent plasma, and a duty to disclose their dangerous and irresponsible plasma collection practices. Independent of any special relationship of confidence or trust, Defendants had a duty not to conceal the dangers of their products to Plaintiff and his physicians.

88. Misrepresentations made by Defendants about the health and safety of their factor concentrate products independently imposed a duty upon Defendants to fully and accurately disclose to the hemophiliac community, including Plaintiff and physicians, the true health and safety risks related to Factor VIII and Factor IX and its constituent plasma, and a duty to disclose their dangerous and irresponsible plasma collection practices.

89. In connection with their Factor VIII and Factor IX products, Defendants fraudulently and intentionally concealed important and material health and safety product risk

information from Plaintiff, the hemophiliac community, and treating physicians, all as alleged in this Complaint.

90. Any of the following is sufficient to independently establish Defendants' liability for fraudulent omission and/or concealment:

a. Defendants fraudulently concealed the health and safety hazards, symptoms, diseases and/or health problems associated with their Factor VIII and Factor IX blood products and related plasma collection activities;

b. Defendants fraudulently concealed the practice of using unsuitable plasma from unsuitable donors in the manufacture of their Factor VIII and Factor IX blood products;

c. Defendants fraudulently concealed their practice of avoiding the use of available technology to detect viruses in their Factor VIII and Factor IX blood products and the components thereof;

d. Defendants fraudulently concealed their practice of avoiding the use of available technology to destroy viruses in their Factor VIII and Factor IX blood products and the components thereof; and/or

e. Defendants fraudulently concealed information about the known comparative risks and benefits of the use of their Factor VIII and Factor IX and the relative benefits and availability of alternate products and therapies.

91. Defendants knew that Plaintiff, the hemophiliac community, and physicians would regard the matters Defendants concealed to be important in determining a course of treatment, including the decision whether to use their Factor VIII and/or Factor IX blood products.

92. As a direct and proximate result of Defendants' fraudulent concealment and suppression of material health and safety risks relating to their Factor VIII and Factor IX blood products and of Defendants' dangerous and irresponsible plasma collection practices, Plaintiff has suffered and will continue to suffer injury, harm and economic loss. As the direct, proximate and legal result of the Defendants' fraudulent concealment and suppression of material health and safety risks relating to their Factor VIII and Factor IX blood products and of Defendants' dangerous and irresponsible plasma collection practices, Plaintiff has been injured and has incurred damages, including but not limited to permanent physical injuries to his person,

medical and hospital expenses in the past, past disability, past loss of use of the body, and past physical and mental pain and suffering; and will incur in the future medical and hospital expenses, permanent disability, loss of use of the body, physical and mental pain and suffering, and loss of the enjoyment of life.

93. Plaintiff is therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

94. Defendants' conduct, as alleged above, was malicious, intentional and outrageous and constituted willful and wanton disregard for the rights or safety of others. Such conduct was directed specifically at Plaintiff and warrants an award of punitive damages.

95. Plaintiff is informed and believes that Defendants utilize retention policies that provide for scheduled destruction of documents and other items, which may result in the knowing, negligent, or inadvertent destruction of documents, data, and materials relevant and necessary to adjudication of this action, including, but not limited to, records identifying batch or lot numbers of Defendants' products shipped to particular treatment facilities, which may facilitate product tracing. This risk warrants an order from this Court that such evidence (including all documents, data compilations, and tangible things within the meaning of Rule 26 of the Federal Rules of Civil Procedure) be preserved and maintained for use in these proceedings.

SECOND CLAIM FOR RELIEF

BREACH OF IMPLIED WARRANTY

96. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further alleges as follows:

97. Defendants' factor concentrate products were intentionally designed, manufactured, promoted, distributed and sold to be introduced into the human body.

98. Defendants breached the implied warranties of merchantability and fitness because Defendants' factor concentrate products cannot pass without objection in the trade, are unsafe, are not merchantable, are unfit for their ordinary use when sold, and are not adequately packaged and labeled.

99. Plaintiff is therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

THIRD CLAIM FOR RELIEF

NEGLIGENCE

100. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further alleges as follows:

101. Defendants marketed their Factor VIII and/or Factor IX blood products to and for the benefit of Plaintiff, and knew or should have known that Plaintiff would use their Factor VIII and/or Factor IX blood products.

102. Defendants owed Plaintiff duties to exercise reasonable or ordinary care under the circumstances in light of the generally recognized and prevailing best scientific knowledge.

103. Through the conduct described in the foregoing and subsequent paragraphs of this Complaint, Defendants breached their duties to Plaintiff. The following sub-paragraphs summarize Defendants' breaches of duties to Plaintiff and describe categories of acts or omissions constituting breaches of duties by Defendants. Each and/or any of these acts or omissions establishes an independent basis for Defendants' liability in negligence:

a. Failure to exercise reasonable care in producing Factor VIII and Factor IX blood products that were free of viruses, including the virus that causes Hepatitis C;

b. Failure to exercise reasonable care in assuring that only suitable plasma would be used in manufacturing their Factor VIII and Factor IX blood products;

c. Failure to exercise reasonable care in testing plasma used in manufacturing their Factor VIII and Factor IX blood products for viral contamination;

d. Failure to exercise reasonable care in recruiting and screening donors of plasma used in their manufacture of Factor VIII and Factor IX blood products;

e. Failure to reasonably employ anti-viral techniques, including solvent and/or detergent treatment, in the manufacture of their Factor VIII and Factor IX blood products;

f. Unreasonable overpromotion of their Factor VIII and Factor IX blood products;

g. Understating the relative value of hemophilia treatments that constituted alternatives to their Factor VIII and Factor IX blood products;

h. Failure to warn physicians, Plaintiff, and the hemophilia community of the dangers associated with their Factor VIII and Factor IX blood products and/or the viruses and foreign bodies contained within the plasma used in manufacturing their Factor VIII and Factor IX blood products;

i. Failure to exercise reasonable care by complying with federal regulations then applicable to plasma collection and the manufacture of Factor VIII and Factor IX blood products;

j. Failure to exercise reasonable care in disseminating information about their methods of manufacturing their Factor VIII and Factor IX blood products and the risks that were created by said methods; and

k. Failure to exercise reasonable care in recalling their Factor VIII and Factor IX blood products.

104. Defendants knew, or should have known, that due to their failure to use reasonable care, Plaintiff and other people with hemophilia would use and did use Defendants' Factor VIII and/or Factor IX products to the detriment of their health, safety and well-being.

105. As the direct, proximate and legal result of the Defendants' negligence, Plaintiff has been injured and has incurred damages, including but not limited to permanent physical injuries to his person, medical and hospital expenses in the past, past disability, past loss of use of the body, and past physical and mental pain and suffering; and will incur in the future medical and hospital expenses, permanent disability, loss of use of the body, physical and mental pain and suffering, and loss of the enjoyment of life.

106. Plaintiff is therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

107. Defendants' conduct, as alleged above, was malicious, intentional and outrageous, and constituted willful and wanton disregard for the rights or safety of others. Such conduct was directed specifically at Plaintiff and warrants an award of punitive damages.

FOURTH CLAIM FOR RELIEF

NEGLIGENCE PER SE

108. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further alleges as follows:

109. Defendants violated applicable federal statutes and regulations relating to prescription drugs. Plaintiff is a person whom these statutes and regulations were meant to protect.

110. Defendants' violation of these statutes or regulations constitutes negligence per se.

111. Defendants' violation of these statutes or regulations was the direct, proximate and legal cause of Plaintiff's injuries and damages. As the direct and legal result of the Defendants' negligence, Plaintiff has been injured and has incurred damages, including but not limited to permanent physical injuries to his person, medical and hospital expenses in the past, past disability, past loss of use of the body, and past physical and mental pain and suffering; and will incur in the future medical and hospital expenses, permanent disability, loss of use of the body, physical and mental pain and suffering, and loss of the enjoyment of life.

112. Plaintiff is therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

113. Defendants' conduct, as alleged above, was malicious, intentional and outrageous and constituted willful and wanton disregard for the rights or safety of others. Such conduct was directed specifically at Plaintiff and warrants an award of punitive damages.

VII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Defendants as follows:

114. For compensatory damages sustained by Plaintiff against Defendants in an amount to be determined at trial;

115. For punitive and exemplary damages according to proof against Defendants;

116. For an award of prejudgment interest, costs, disbursements and reasonable attorneys' fees;

117. For injunctive relief in the form of an order requiring Defendants to preserve all relevant documents; and

118. For such other and further relief as the Court deems equitable or appropriate under the circumstances.

Dated: May 16, 2007

Heather A. Foster

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DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all issues stated.

Dated: May 16, 2007

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